

## REMARKS/ARGUMENTS

### **35 USC §112**

The Office rejected **claims 1 and 3-20** under 35 USC 112, first paragraph as failing to comply with the enablement requirement. More specifically, the office argued that the term "...sub-ripe, non-green dried *Coffea spec.* (coffee) cherry..." would not find corresponding written description.

The applicant respectfully disagrees and points to the specification page 3, line 20 to page 4, line 3, and page 8, line 28 to page 9, line 2 in which specific description for the objected term is provided. Nevertheless, the applicant amended claims 1 and 15 to characterize the *Coffea spec.* (coffee) cherry as being "primarily red or almost ripe". These terms find express definition in the specification on page 8, line 28 to page 9, line 1.

With respect to the examiner's argument on page 4 of the office action that it would be "... readily clear that Applicant intended to direct the instantly claimed invention to a cosmetic composition comprising whole cherry Coffea sp., wherein the cherry is sub-ripe, green and dried and having a claim-designated mycotoxin level....", it is noted that the office's statement is a mischaracterization with regard to the color of the coffee cherry. As can be taken from page 8, line 28 to page 9, line 2, and Table 1 of page 9, primarily red or almost ripe coffee cherries are clearly within the scope of the claimed invention. Therefore, in view of the amendments and arguments provided above, the office's rejection should be withdrawn.

The Office rejected **claims 1, and 3-20** under 35 USC 112, second paragraph as failing to comply with the enablement requirement. More specifically, the office argued that the term "...sub-ripe, non-green *Coffea spec.* (coffee) cherry..." would be unclear as such term would allegedly be in conflict with the use of the term "coffee cherry" in the art.

The applicant respectfully disagrees and notes that it is well established that an *applicant is entitled to be his or her own lexicographer* and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994). Indeed, *where an explicit definition is*

*provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim.* *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999).

Applied to the instant rejection, it is the applicant's position that the term "primarily red or almost ripe *Coffea spec.* (coffee) cherry" is *defined with sufficient clarity* in the applicant's specification to be so understood by a person of experience in the field of the invention (see also: *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998)). Moreover, it is pointed out that "...the specification should also be relied on for more than just explicit lexicography or clear disavowal of claim scope to determine the meaning of a claim term when applicant acts as his or her own lexicographer; the meaning of a particular claim term may be defined by implication, that is, according to the usage of the term in the context in the specification..." (see *Phillips v. AWH Corp.*, \*>415 F.3d 1303<, 75 USPQ2d 1321 (Fed. Cir. 2005) (en banc)). In this case, the express definitions and examples provided by the applicant provide specific meaning to the claim objected term. Thus, in view of the amendments and arguments provided above, the office's rejection should be withdrawn.

### **Claim Objections**

The Office objected to **claim 7** as failing to properly limit the scope since claim 7 was not dependent on any other claim. The applicant agrees and amended claim 7 to depend on claim 1. The objection should therefore be overcome.

The Office objected to **claim 9** for apparent omission of a verb in line 3 of the claim and suggested addition of the verb --is-- after "cherry". The applicant disagrees and notes that claim 9 specifies the amount of the two (or more) classes of compounds in the composition (wherein that composition is prepared from whole *Coffea spec.* (coffee) coffee cherry). In this claim, the two classes of compounds are present in an amount of at least 5 wt% total. The applicant believes that the specific language of claim 9 is clear, and that addition of the term "is" would be confusing.

The Office objected to **claim 15** for an obvious misspelling in line 7 and pointed out that the term "ppm" should read --ppb--. The applicant respectfully disagrees and points to page 2, line 12 and page 3, line 24 of the specification from which it can be seen that the concentration of fumonisins should be below 5ppm.

### **35 USC §103**

The Office rejected **claims 1, 3-5, 8-10, and 12-14** as being obvious over Sceopul (U or N) in view of Johnston et al. (A\*), Soucy (B\*), Bucheli et al. (X2), Mann et al. (C\*), Clifford (V1), Bertrand et al. (U2) and Suzuki (W2), and further in view of Batista et al. (W), Frank (W1), Helferich (W), Romani et al. (X), Codex Committee on Food Additives and Contaminants (X1 or CCFAC) and the United States Food and Drug Administration or USDA (U1). The applicant respectfully disagrees, especially in view of the amendments herein.

(a) As is well known, to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

As amended herein, claim 1 expressly requires that the cosmetic composition comprises "...a *composition...from a whole...coffee cherry*, wherein the...*coffee cherry...is a sub-ripe, primarily red or almost ripe dried...coffee cherry...*". In contrast, Sceopul teaches a cosmetic preparation in which green coffee fruit is washed multiple times after harvest and then pressed to produce a creamy mass that is compounded into the cosmetic preparation. Thus, *Sceopul fails to teach that the coffee cherry is (1) sub-ripe and primarily red or almost ripe, and (2) is a dried coffee cherry*. Indeed, Sceopul teaches against the presently claimed subject matter, and the remaining references fail to remedy these defects for the following reasons.

(b) It is well established that "...teachings of references can be combined only if there is some suggestion or incentive to do so..." (see *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988), and that the need for specificity pervades this authority. Indeed, particular

findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed (see e.g., *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). Even when the level of skill in the art is high, the Office must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. In other words, the Office must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious (see e.g., *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998). Even post-KSR, in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed (USPTO KSR Memo by Margaret A. Focarino, Deputy Commissioner for Patent Operations)

First, the examiner stated that "...prior studies showed that Aspergillus, Penicillium and Fusarium are natural coffee contaminants having the potential to produce aflatoxins, ochratoxins, and fumonisin which are detrimental to the quality and safety of the final product..." and argued that such finding would have motivated a person of ordinary skill in the art to modify Scopul to use a primarily red or almost ripe dried coffee cherry. In support of this proposition, the office cited Batista, Frank, Helferich, Romani, and FDA. Unfortunately, none of the cited art properly supports the offices obviousness argument.

Regarding **Batista** it is noted that this reference is entirely concerned with mycotoxins on processed *green coffee beans* and as such fails to address the issue of green coffee cherry versus primarily red or almost ripe coffee cherry. Moreover, Batista is completely *silent on the use of a dried coffee cherry*. Moreover, Batista expressly teaches the well known use of a hypochlorite solution for sterilization of the beans, which effectively reduces the mycotoxin levels (see e.g., abstract). Lastly, **Batista expressly teaches (page 298, right column, paragraph 4.3.) that none of the coffee bean samples tested exceeded the regulatory limits for mycotoxins.** Thus, Batista not only fails to provide any significance with respect to the degree of coffee cherry maturity, but also fails to provide any motivation for the alleged modification of Scopul.

Regarding Frank it is noted that Frank is once more concerned with mycotoxin analysis on green beans, which is entirely inconsistent with a sub-ripe and primarily red or almost ripe dried coffee cherry. Moreover, Frank is completely *silent on the use of a dried coffee cherry*. While the examiner provided several passages from Frank, it remained unclear as to how these passages would have motivated the person of ordinary skill in the art to modify Sceopol. On the contrary Frank teaches that *cherries in the wet state are not prone to Aspergillus development* (page 7, item g) and thus teaches against a dried coffee cherry as presently claimed. Similarly, Frank teaches that *outer fruit tissues contain more frequently A. ochraceus than beans* (page 7, item g, and page 9, item 26), which *teaches against use of a coffee cherry*.

Regarding Helperich it is noted that *this reference does not teach that aflatoxins are contaminants on agricultural crops such as coffee as stated by the office*. All Helperich teaches is that *aflatoxins are prevalent in stored coffee beans*. Moreover, Helperich also teaches that various active *decontamination procedures* are known in the art to reduce aflatoxins content. Therefore, such teaching entirely fails to provide any motivation to modify Sceopol as proposed by the examiner. Still If anything, Helperich motivates to decontaminate an aflatoxin containing composition. On a finer note, Helperich is concerned with exposure to aflatoxins via ingestion, which is further inconsistent with the presently claimed subject matter. Lastly, Helperich is entirely *silent on the use of a dried coffee cherry*.

Regarding Romani it is noted that *this reference is yet again concerned with various ochratoxins (OTA) on green coffee beans, and has absolutely nothing to do with sub-ripe, primarily red or almost ripe dried coffee cherries*. As with Helperich, (1) Romani is concerned with exposure to aflatoxins via ingestion, which is inconsistent with the presently claimed subject matter, and (2) Romani is entirely *silent on the use of a dried coffee cherry*. Clearly, Romani fails to provide any motivation to modify Sceopol as suggested by the office.

Regarding FDA it is noted that *FDA merely teaches certain maximum levels for fumonisins in human consumption (i.e., ingestion). FDA is entirely silent on the issue of sub-ripe, primarily red or almost ripe dried coffee cherries*. Once again, there is absolutely nothing in FDA that would provide any motivation to modify Sceopol as suggested by the office.

Therefore, while Batista, Frank, Helferich, Romani, and FDA all discuss mycotoxins in one or another context, none of the references provides any suggestion or motivation to modify Sceopol in a manner such as to arrive at the presently claimed subject matter. Indeed, Batista teaches that mycotoxins are a non-issue and thus fails to motivate any process or selection of raw material to reduce mycotoxins to a specific level. Frank teaches against the use of any coffee cherry as the mycotoxins are found more frequently in the outer fruit tissues, and further teaches against dried coffee cherries as cherries in the wet state are not prone to Aspergillus growth. Helferich motivates to use a decontamination process, while Romani and FDA are immaterial to coffee cherries, let alone dried coffee cherries. It should be pointed out that only Frank addresses a coffee cherry, however, in a manner that teaches against a combination with Sceopol. Batista, Helferich, Romani, and FDA merely discuss coffee beans. Still further, none of the references teaches dried coffee cherries (let alone a composition prepared from dried coffee cherries) as expressly recited in the instant claims.

Second, the examiner stated that "...each of Johnston, Mann and Soucy teaches quick-dry methods for reducing the number of toxicogenic fungal genera and mycotoxin contaminants in whole coffee cherry or an agricultural crop of economic importance wherein mycotoxins may occur..." (office action page 13, first sentence) and argued that quick-drying would "...provide for a more microbially stabilized food product by reducing or killing bacteria and molds present on or in coffee plant parts, as well as inactivate or substantially reduce mycotoxins..." (office action page 15, lines 9-12). The examiner further cited Buecheli to establish that proper drying of whole fruit coffee would reduce ochratoxins. Once more the applicant respectfully disagrees for various reasons.

Regarding Johnston it should be noted that Johnston is concerned with improvements in quality of green coffee beans using a process in which fermentation of the pulp is avoided. More specifically, Johnston teaches use of *ripe coffee cherries* (e.g., column 2, line 40), which is inconsistent with the presently claimed subject matter. Furthermore, Johnston expressly teaches that the cherries are *preferably pulped prior to the drying process* (e.g., column 2, line 32-34; and column 2, line 53 to column 3, line 5). Thus, while Johnston teaches quick-drying of coffee cherries, it is noted that the coffee cherry is a ripe cherry and that the intent of Johnston is to improve the quality of the bean (e.g., column 2, lines 19-23). There is *absolutely no reference to*

*any presence or reduction of mycotoxins as suggested by the office.* All Johnston teaches is that the quality of green beans can be improved where the coffee cherry is pulped and dried. Therefore, Johnston fails to provide any motivation to modify Secopul as proposed by the office.

Regarding Mann, the applicant notes that *the office once again misstated a reference.* More specifically, the office noted that Mann would teach a method of lowering an aflatoxins level using a heat treatment (office action, page 13, line 7 et seq.), however, fails to provide critical information as Mann teaches that (a) the *heat treatment is optional* (b) that the *reduction in aflatoxins is effected by the use of methylamine* (e.g., column 2, lines 14-18). Still further, it should be noted that *Mann fails to teach detoxification of coffee cherries* (see e.g., column 3, line 30 et seq.). If anything, it should be appreciated that Mann motivates to detoxify aflatoxins-containing items using a solvent-based process, but clearly not a quick-dry process as offered by the examiner.

Regarding Soucy, the applicant notes that *this reference is yet again entirely devoid of any teaching of drying of a coffee cherry*, but instead teaches various devices and methods of drying coffee beans. Nevertheless, the examiner stated that Soucy would teach a process "...for drying whole coffee beans, coca beans (whole coffee cherry), and various grains..." (office action, page 13, line 11). How a coca bean could be considered a whole coffee cherry is unclear to the applicant. Clarification is respectfully requested. The examiner further stated that the drying process would significantly reduce the moisture content (office action, page 13, line 14). While the applicant agrees with such assessment, it is unclear how such statement relates to the claimed subject matter.

Regarding Buecheli it is noted that *this reference expressly teaches that husks and overripe cherries are the main source of OTA* (see e.g., abstract), which clearly *teaches away from use of the whole coffee as presently claimed.* This is also reflected in the reference stating that *ripe coffee cherries of good quality were basically free of OTA* (page 1360, left column, second paragraph), and that *non-ripe and ripe coffee cherries contained only trace amounts of OTA in the green coffee* (page 1359, right column, third paragraph). Furthermore, it is noted that Buecheli expressly teaches that "...there was no evidence for generation of OTA on unripe cherries under any of the four drying conditions tested..." (page 1361, right column, second

paragraph). Clearly, Buecheli specifically teaches that the drying conditions are immaterial and the office's argument is therefore at best improper and ill supported.

Consequently, none of Johnston, Mann, Soucye, and Buecheli provide any motivation to modify Sceopol as suggested by the office. Johnston teaches away from the claimed subject matter by using ripe coffee cherries from which the pulp is removed prior to drying, while Mann advocates specific solvent-based processes to decontaminate the coffee cherry, and Soucy fails to have any significance to the claimed subject matter. Lastly, Buecheli specifically provides data establishing that drying processes have no impact on mycotoxin levels, thus effectively mooting the examiner's arguments and above references.

Third, the examiner relied on Clifford, Bertrand, and Suzuki to establish certain claim elements with regard to chemical components in the coffee cherry. However, these references yet again fail to properly provide a basis for an obviousness rejection.

Regarding Clifford, it is noted that Clifford is concerned with chemical analysis of *immature green coffee beans*, which is entirely inconsistent with a sub-ripe, primarily red or almost ripe dried coffee cherry as presently claimed. Consequently, Clifford is immaterial to the claimed subject matter.

Regarding Bertrand, the examiner stated that the content of CQA drastically increased at the end of the growth period of the coffee fruit. However, the office conveniently ignored data showing substantial or even dramatic decrease in the content of other polyphenolic compounds as can be readily taken from Tables 1 and 2. If anything, it should be apparent that there is a high variability of polyphenolic compounds in a coffee cherry over the period of fruit development, and that the exact amounts will depend on the particular compound. However, such teaching is immaterial at best to the claimed subject matter.

Regarding Suzuki, the examiner cited data on caffeine, theobromine, and theophylline during development of the seed and pericarp in coffee fruit. However, how such data bear on the claimed subject matter is not clear. Clarification is respectfully requested.

Therefore, while Clifford, Bertrand, and Suzuki report content of various polyphenolic compounds in coffee in distinct stages of ripening, none of the data consistently provide any

indication that one or another ingredient will substantially, consistently, and predictably increase. Thus, it should be noted that Clifford, Bertrand, and Suzuki fail to remedy the defects of the combination of Sceopul with Batista, Frank, Helferich, Romani, and FDA and/or Johnston, Mann, Soucey, and Buecheli.

As provided above, the combined teachings as a whole fail to suggest or motivate a person of ordinary skill in the art to modify Sceopul as proposed by the examiner. Therefore, the rejection of claims 1, 3-5, 8-10, and 12-14 as being obvious over the cited art should be withdrawn.

Lastly, and of substantial significance, the applicant points out that the claimed cosmetic composition must include a *composition that is prepared from a dried coffee cherry* (which also must be sub-ripe primarily red or almost ripe). Such element is far from being trivial. As coffee cherries contain (among other compounds) polyphenolic compounds, and as most polyphenolic compounds are highly prone to oxidation and polymerization (which can be readily observed in the browning of an apple or banana that is cut open), there are various critical differences in preparations obtained by using fresh fruit (as taught by Sceopul) and a dried fruit (as presently claimed). First, *any extract prepared from maceration of fresh fruit is immediately subjected to oxidation, polymerization and degradation*. In contrast, compositions prepared from a dried fruit will not encounter such difficulties. Second, *any extract prepared from maceration of fresh fruit is necessarily limited to the content in the initial aqueous phase obtained from maceration*. In contrast, compositions prepared from a dried fruit are amenable to all types of solvents, aqueous and non-aqueous alike (and all mixtures thereof). Third, *any extract prepared from maceration of fresh fruit is necessarily diluted by the water content in the fruit and will need concentration in a downstream processing step*. In contrast, compositions prepared from a dried fruit can be extracted with desirably small quantities of solvent and may so allow production of concentrated extracts without enrichment steps. Lastly, *processing of the fresh fruit is in most cases limited to the point of harvest* and requires further processing of the macerate. In contrast, processing of the dried fruit allows shipping of the desired components in the natural environment at relatively small weight. Further process steps can be implemented in any locale.

The Office rejected claims 1, 3-5, 8-10, and 12-14 as being obvious over Sceopol (U or N) in view of Johnston et al. (A\*), Soucy (B\*), Bucheli et al. (X2), Mann et al. (C\*), Clifford (V1), Bertrand et al. (U2) and Suzuki (W2), and further in view of Batista et al. (W), Frank (W1), Helferich (W), Romani et al. (X), Codex Committee on Food Additives and Contaminants (X1 or CCFAC) and the United States Food and Drug Administration or USDA (U1), and further view of the Free Dictionary by Farlex.

At the outset, the **applicant assumes that the office intended to reject claims 15-20.** Nevertheless, and based on this assumption, the applicant still respectfully disagrees, especially in view of the amendments herein.

With respect to the combination of Sceopol, with Johnston et al., Soucy, Bucheli et al., Mann et al., Clifford, Bertrand et al., Suzuki, Batista et al., Frank, Helferich, Romani et al., Codex Committee on Food Additives and Contaminants and the United States Food and Drug Administration or USDA, *the same defects and considerations as noted above apply* and are not reiterated here. It should be noted that *the remaining cited reference fails to remedy the defects pointed out above.* Indeed, all Farlex provides is a generic definition that lacks any teaching supporting the step of providing the claimed information. It should be noted that numerous cosmetic formulations are marketed without pointing to a specific ingredient or group of ingredients, but rather advertise a desired effect.

The Office further rejected claims 1, 3-6, and 8-14 as being obvious over as being obvious over Sceopol (U or N) in view of Johnston et al. (A\*), Soucy (B\*), Bucheli et al. (X2), Mann et al. (C\*), Clifford (V1), Bertrand et al. (U2) and Suzuki (W2), and further in view of Batista et al. (W), Frank (W1), Helferich (W), Romani et al. (X), Codex Committee on Food Additives and Contaminants (X1 or CCFAC) and the United States Food and Drug Administration or USDA (U1), and further view of Fischer et al. (V3), Clifford et al. (W3) and Coleman et al. (X3), and further in view of Pineau et al. (E\*), Huang et al. (U4) and Stuckler et al. (O).

The **applicant assumes that the office intended to reject claims 6 and 8.** Nevertheless, and based on this assumption, the applicant still respectfully disagrees, especially in view of the amendments herein.

Once more, and with respect to the combination of Scopul, with Johnston et al., Soucy, Bucheli et al., Mann et al., Clifford, Bertrand et al., Suzuki, Batista et al., Frank, Helferich, Romani et al., Codex Committee on Food Additives and Contaminants and the United States Food and Drug Administration or USDA, *the same defects and considerations as noted above apply* and are not reiterated here. It is also noted that *the remaining cited references fail to remedy the defects pointed out above.*

Regarding Fisher it should be noted that this reference is drawn to the chemical analysis of *polysaccharides in green coffee beans*, which is once more immaterial to the claimed subject matter. While Fisher teaches that ethanolic extraction can be used to isolate low molecular weight carbohydrates, it is pointed out that the *starting material is depulped and deparched coffee beans and not a dried coffee cherry*. On a finer note, it should be appreciated that the monosaccharides in Fisher can also be isolated using water. Likewise, Clifford uses *dry processed green coffee beans* for analysis of chlorogenic acids, and Coleman teaches isolation of pectins from coffee mucilage. Therefore, while the above references teach use of water and ethanol as solvents for specific compounds, none of the cited art is relevant with respect to the claimed starting material (*i.e.*, the dried coffee cherry) in claim 6.

Likewise, Pineau teaches use of viscous alginates in cosmetic formulations. It is unclear to the applicant which portion of Pineau could form a proper basis of the rejection of claim 8. Clarification is respectfully requested. Similarly, Huang was cited as teaching topical skin compositions that include chlorogenic acid. However, it should be noted that Huang fails to teach a cosmetic composition as Huang is concerned with inhibition of TPA-induced tumor promotion. Huang is non-analogous art. Stuckler teaches use of trigonelline in a topical formulation, however, teaches that trigonelline is prepared from the seed of Trigonella foenum gracum. Once more, and in addition to the defects pointed out above, the cited art fails to teach or suggest the claimed subject matter of claim 8.

**Request For Allowance**

Claims 1, 3-18, and 20 are pending in this application. The applicant requests allowance of all pending claims.

Respectfully submitted,  
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